K 130332

SECTION 6: 510(k) Summary

MAY 3 1 2013

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Ortho-Clinical Diagnostics, Inc.
Address	100 Indigo Creek Drive Rochester, New York 14626
Phone number	(585) 453-3962
Fax number	(585) 453-3368
Establishment Registration Number	1319809
Name of contact person	Gaozhen Hang
Date prepared	February 8, 2013
Name of device	
Trade or proprietary name	VITROS Chemistry Products TRIG Slides
Common or usual name	Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides
Classification name	Triglyceride test system
Classification panel	Clinical Chemistry
Regulation	21 CFR 862.1705
Product Code(s)	CDT
Legally marketed device(s) to which equivalence is claimed	The VITROS Chemistry Products TRIG Slides (modified) are substantially equivalent to the VITROS Chemistry Products TRIG Slides (current). The FDA cleared the VITROS Chemistry Products TRIG Slides on August 3, 1981 (k812029).

Reason for 510(k) submission	A Special 510(k) for a modification to own device which does not include a change in intended use or fundamental technology. The biological source of lipase, one of the reactive ingredients used in VITROS Chemistry Products TRIG Slides, is being changing from the fungi *Candida rugosa* to the microorganism *Pseudomonas*. It enhances supply chain continuity. NOTE: The exact material (active ingredients-Lipase) has been used on this device type, so, per guidance, a special 510(k) can be used. The source of the active ingredient (Lipase, E.C. 3.1.1.3) changed from a from *Candia rugosa* to *Pseudomonas*; however, the lipase is the same material, has the same E.C. number, and has the same function as the lipase used in the current VITROS TRIG Slides for over 31 years.
Device description	The VITROS TRIG assay is performed using the VITROS Chemistry Products TRIG Slides and the VITROS Chemistry Products Calibrator Kit 2 on the VITROS Chemistry Systems. The VITROS TRIG Slide is a multi-layered, analytical element coated on a polyester support. The method is based on an enzymatic detection. All reactions necessary for a single quantitative measurement of triglyceride take place within the multi-layered analytical element of a VITROS Chemistry Products TRIG Slide. A drop of sample fluid is metered onto the slide and a reaction occurs which ultimately results in the oxidation of a leuco dye by hydrogen peroxide. The concentration of triglyceride in the sample is determined by measuring the absorbance of the dye by reflectance spectrophotometry.
Intended use of the device	For *in vitro* diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS® Systems.
Indications for use	For *in vitro* diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS® Systems. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Summary of the technological characteristics of the device compared to the predicate device		
Characteristic	New Device [VITROS TRIG Slide (Modified)]	Predicate [VITROS TRIG Slide (Current) [k812029]
Intended Use	No Change	For *in vitro* diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.
Basic Principle	No Change	Enzymatic Endpoint test type utilizing reflectance spectrophotometry
Concentrations of VITROS TRIG Slide Reactive Ingredients per cm-squared	Lipase (***Pseudomonas*** E.C. 3.1.1.3) 0.08 U	Lipase (***Candida rugosa*** E.C. 3.1.1.3) 0.15 U
	No Change	Peroxidase (horseradish root E.C.1.11.1.7) 0.52 U; glycerol kinase (Cellulomonas sp., E.C.2.7.1.30) 0.35 U; L-α-glycerophosphate oxidase (*Pediococcus sp.*, E.C.1.1.3.-) 0.19 U; Triton X-100 0.62 mg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimenthylaminophenyl) imidazole (leuco dye) 0.04 mg; and adenosine triphosphate 0.14 mg.
Sample volume	No Change	5.5 µL
Sample type	No Change	Serum, plasma
Assay Range Serum, Plasma	No Change	10.0-525.0 mg/dL
Incubation time and temperature	No Change	5 minutes at 37°C

Summary of design control activities conducted in relation to the device modification
The Ortho-Clinical Diagnostics, Inc. procedure for risk management is based on ISO 14971, Medical Devices – Application of Risk Management to Medical Devices and references CDRH Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management. The risk analysis method used to assess the impact of the device modification was a Hazard Analysis. The following performance characteristics: accuracy, precision, linearity, potential interferents, long term and on-analyzer stability, limit of detection and specimen type were considered for potential hazards. Validation and verification testing were conducted and the modified device met the pre-determined acceptance criteria for all the performance testing. The modification does not negatively impact the performance of the device or the safety and effectiveness of the device.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products TRIG Slides (modified) for use with human serum and plasma is substantially equivalent to the predicate (unmodified VITROS TRIG Slides) and is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2013

Ortho-Clinical Diagnostics, Inc.
C/O Gaozhen Hang
100 Indigo Creek Drive
ROCHESTER NY 14626-5101

Re: K130332
Trade/Device Name: VITROS Chemistry Products TRIG Slide
Regulation Number: 21 CFR 862.1705
Regulation Name: Triglyceride test system
Regulatory Class: I, meets limitations of exemption per 21 CFR 862.9(c)(4)
Product Code: CDT
Dated: May 06, 2013
Received: May 09, 2013

Dear Gaozhen Hang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol E. Benson -S for

Courtney H. Lias, Ph.D.
Director,
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130332

Device Name: VITROS® Chemistry Products TRIG Slide

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For *in vitro* diagnostic use only. VITROS Chemistry Products TRIG Slides quantitatively measure triglyceride (TRIG) concentration in serum and plasma using VITROS® Systems. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler-S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k130332